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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,373	09/22/2003	Hidehiro Yamazaki	033025-006	5015

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/665,373	Applicant(s) YAMAZAKI, HIDEHIRO	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 4, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with metabolic acidosis comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.
- II. Claim 5, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with burn injury comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, *digest* 13, 514/23, 574.
- III. Claim 6, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with hemorrhagic shock comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride

ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 521, 574.

- IV. Claim 7, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with multiple organ failure comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.
- V. Claim 8, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with systemic inflammatory reaction comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.
- VI. Claim 9, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient under operation or post-operative

patient comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.

VII. Claim 10, drawn to method for controlling water and electrolyte balance and acid-base equilibrium of a patient with hypohydremia comprising administering continuously a preparation solution containing a specially formulated mixture of sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose at a rate of 2-60 ml/kg/hour, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.

VIII. Claims 11-14, drawn to a composition that contains sodium ion, potassium ion, bicarbonate ion, chloride ion, calcium ion, magnesium ion, citrate ion and glucose, classified in multiple subclasses in classes 424 and 514, such as for example, 424/677-683, 686-687, 693, 717, 722, 514/23, 574.

Claims 1-3 link inventions I to VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions

shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons: Inventions of Group VIII and I, II, III, IV, V, VI or VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, as evidenced by applicant's own claims. Applicant's claims 4-10 are evidence that the composition can be used to treat different patient pools with different conditions of different etiologies. Alternatively, the composition can be used in a another materially different process, such as in dialysis.

In addition to the distinctness of the inventions as set forth above, the burden of searching and examining more than one invention group would be serious. For example, searching for the composition already rises up to a level that would be serious burden because there is no efficient way to search for numerical values of concentrations of 8 different composition ingredients. Each composition ingredient has to be laboriously compared with prior art compositions to see whether they match or overlap. This is a line-by-line, needle in a haystack type of searching. No efficient searching technique is available to cull through the thousands of documents that contain and disclose applicant's ingredients. With respect to the restriction between the seven different method inventions, it is noted that the subject patients in each of the inventions suffer from different conditions. Even though the classification of the method inventions overlap substantially, the required non-patent literature search would not be coextensive since different disorders or conditions are involved. In the absence of a nexus type teaching, the Examiner would have to search for and make out a case, with proper documentation, that each of the subject patients would be expected to be treated by prior art composition(s), if appropriate. Otherwise, applicant would surely surmount a vigorous challenge if the Examiner were to assert that a treatment protocol taught to be suitable for, say burn patients, would be obvious for multiple organ failure patients. Hence, each of the different patient types must be searched separately and separate rationale must be advanced for patentability or unpatentability of each invention group.

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Given the burden of searching and examining just one invention group under the facts of this application, the additional burden represented by other distinct invention group(s) would be undue burden.

Therefore, for reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

A telephone call was made to Mr. Grudziecki (no longer at the law firm of record) and Ms. Dadio on 1/10/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

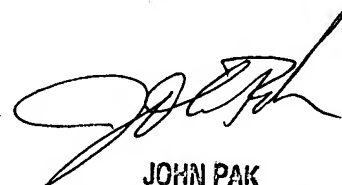
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
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